

# General

## Guideline Title

ACR Appropriateness Criteria® Crohn disease.

# Bibliographic Source(s)

Kim DH, Carucci LR, Baker ME, Cash BD, Dillman JR, Feig BW, Fowler KJ, Gage KL, Noto RB, Smith MP, Yaghmai V, Yee J, Lalani T, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® Crohn disease [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 22 p. [140 references]

### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Fidler JL, Rosen MP, Blake MA, Baker ME, Cash BD, Charron M, Greene FL, Hindman NM, Jones B, Katz DS, Lalani T, Miller FH, Small WC, Sudakoff GS, Tulchinsky M, Yaghmai V, Yee J, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® Crohn disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 14 p. [117 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

# Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Crohn Disease

<u>Variant 1</u>: Adult. Acute initial presentation. Fever, severe abdominal pain, vomiting, leukocytosis. Suspected Crohn disease.

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen and pelvis with IV contrast	8	The procedures are equivalent alternatives, and only one should be performed.	
Rating Scaleapta, 3 Usually not appropriat	e; \$4,5,6 May be appropriate;	7,19.2 Month of the proprieto alternatives, and only	*Relative

Radiologic Procedure	Rating	one should be performed. Severe vomiting may preclude the required intake for this examination.	RRL*
		product and required manner for any community	
MR enterography	6	This procedure may not be well tolerated in acute setting.	О
MRI abdomen and pelvis without and with IV contrast (routine)	5	This procedure may be an option if patient cannot receive IV iodinated contrast for CT.	О
X-ray abdomen	5	Consider this procedure if the patient is unstable and there is high suspicion for perforation.	
CT abdomen and pelvis without IV contrast	5	This procedure is only appropriate if the patient cannot receive IV contrast. Oral contrast should be given; radiodense is preferred.	
US abdomen and pelvis	5	This procedure is dependent on operator expertise and patient body habitus.	О
MRI abdomen and pelvis without IV contrast (routine)	4	This procedure is preferred over CT in pregnant patients.	О
CT abdomen and pelvis without and with IV contrast	3		
CT enteroclysis	3	Little role in the acutely ill patient.	
MR enteroclysis	3	Little role in the acutely ill patient.	0
X-ray small-bowel follow-through	3		
X-ray contrast enema	3		
Tc-99m HMPAO leucoscintigraphy	2		
FDG-PET/CT abdomen and pelvis	2		
Rating Scale: 1,2,3 Usually not appropria	ate; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 2</u>: Adult. Nonacute or indolent initial presentation. Mild to moderate abdominal pain or cramping. Suspected Crohn disease.

Radiologic Procedure	Rating	Comments	RRL*
CT enterography	9	The procedures are equivalent alternatives, and only one should be performed.	
MR enterography	9	The procedures are equivalent alternatives, and only one should be performed.	О
CT abdomen and pelvis with IV contrast	6	Consider this procedure if the patient cannot tolerate oral contrast requirements of CT enterography.	
CT enteroclysis	6	This procedure requires specialized expertise that may not be available at all centers.	
MRI abdomen and pelvis without and with IV contrast (routine)	6	This procedure may be an option if the patient is unable to undergo CT enterography or MR enterography.	O
CT abdomen and pelvis without IV contrast	5		
MR enteroclysis	5	This procedure requires specialized expertise that may not be available at all centers.	О
X-ray small-bowel follow-through	5		
US abdomen and pelvis	5		0
MRI abdomen and pelvis without IV contrast (routine)	4	This procedure is preferred over CT in pregnant patients.	О
X-ray contrast enema	4		
X-ray abdomen	3		
CT abdomen and pelvis without and with IV contrast	3		
Tc-99m HMPAO leucoscintigraphy	2		
Rating Scale: 1.2.3 Hsually not appropri	ate: 456 May be annronriate	· 7 & 0 Hsually appropriate	*Relative

EDG-PET/CT abdomen and pelvis	Rating	Comments	RRL*
Rating Scale: 1,2,3 Usually not appropriate	e; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative
			Radiation
			Level

<u>Variant 3</u>: Child. Initial presentation. Suspected Crohn disease.

Radiologic Procedure	Rating	Comments	RRL*
MR enterography	9	The procedures are equivalent alternatives, and only one should be performed.	0
CT enterography	8	The procedures are equivalent alternatives, and only one should be performed.	
CT abdomen and pelvis with IV contrast	6	This procedure is a good choice if the patient cannot tolerate MR enterography or CT enterography due to a severe acute presentation. It may be less helpful in indolent Crohn disease presentations.	
MRI abdomen and pelvis without and with IV contrast (routine)	6		O
US abdomen and pelvis	6		О
CT abdomen and pelvis without IV contrast	5		
MRI abdomen and pelvis without IV contrast (routine)	5		0
X-ray small-bowel follow-through	5		
X-ray abdomen	5	Consider this procedure if the patient is unstable in an acute presentation and there is high suspicion for perforation.	
CT enteroclysis	4		
MR enteroclysis	4		О
Rating Soutest 2031 Asually not appropri	ate; 34,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen and pelvis without and with IV contrast	3		
Tc-99m HMPAO leucoscintigraphy	2		
FDG-PET/CT abdomen and pelvis	2		
Rating Scale: 1,2,3 Usually not appropriate	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 4</u>: Adult with known Crohn disease; acute exacerbation such as fever or increasing abdominal pain or leukocytosis.

Radiologic Procedure	Rating	Comments	RRL*
CT enterography	9	The procedures are equivalent alternatives, and only one should be performed.	
CT abdomen and pelvis with IV contrast	8	The procedures are equivalent alternatives, and only one should be performed. It is a good choice if the patient is unable to tolerate the oral contrast requirements of CT enterography.	
MR enterography	8	The procedures are equivalent alternatives, and only one should be performed. Image quality may be degraded by patient severity of illness.	0
MRI abdomen and pelvis without and with IV contrast (routine)	6	This procedure may be helpful when the patient is unable to tolerate oral contrast requirements of MR enterography.	O
CT abdomen and pelvis without IV contrast	5		
MRI abdomen and pelvis without IV contrast (routine)	5		О
X-ray abdomen	5		
Rating dance half pelsisally not appropri	ate; \$1,5,6 May be appro	opriate; 7,190	CRelative

Radiologic Procedure	Rating	patient booly habitus.	RRL*
X-ray small-bowel follow-through	4		
CT abdomen and pelvis without and with IV contrast	3		
CT enteroclysis	3	This procedure has little role in the acutely ill patient.	
MR enteroclysis	3	This procedure has little role in the acutely ill patient.	О
X-ray contrast enema	3		
Tc-99m HMPAO leucoscintigraphy	3		
FDG-PET/CT abdomen and pelvis	3		
Rating Scale: 1,2,3 Usually not appropri	ate; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 5</u>: Child with known Crohn disease; acute exacerbation such as fever or increasing abdominal pain or leukocytosis.

Radiologic Procedure	Rating	Comments	RRL*
MR enterography	9	The procedures are equivalent alternatives, and only one should be performed.	О
CT abdomen and pelvis with IV contrast	7	The procedures are equivalent alternatives, and only one should be performed. It is a good option when a child is unable to tolerate MR enterography due to severe acute presentation.	
CT enterography	7	The procedures are equivalent alternatives, and only one should be performed.	
Rand State in and pishail with two appropriates with IV contrast (routine)	te; 64,5,6 May be appropriate;	7,80 Additionally is appropriate if the patient is unable to tolerate oral contrast requirements of MR enterography.	CRelative Radiation Level

R&diologica-Pracedoctvis	Rating	Chis precededure is dependent on operator expertise.	®RL*
CT abdomen and pelvis without IV contrast	5		
MRI abdomen and pelvis without IV contrast (routine)	5		О
X-ray abdomen	5		
X-ray small-bowel follow-through	4		
CT abdomen and pelvis without and with IV contrast	3		
CT enteroclysis	3	This procedure has little role in the acutely ill patient.	
MR enteroclysis	3	This procedure has little role in the acutely ill patient.	О
X-ray contrast enema	3		
Tc-99m HMPAO leucoscintigraphy	2		
FDG-PET/CT abdomen and pelvis	2		
Rating Scale: 1,2,3 Usually not appropri	iate; 4,5,6 May be appropria	tte; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 6</u>: Adult with known Crohn disease; stable, mild symptoms and/or surveillance.

Radiologic Procedure	Rating	Comments	RRL*
MR enterography	9	The procedures are equivalent alternatives, and only one should be performed.	О
Rating Scale: 1.2.3 Usually not appropriat	e: 4.5.6 Mav be appropriate:	7.8.9 Usually appropriate	*Relative

Radiologic Procedure	Rating	The procedures are equivalent alternatives, and only one should be performed.	RRL*
		one should be performed.	
CT abdomen and pelvis with IV contrast	6		
CT enteroclysis	6	This procedure requires specialized expertise that may not be available at all centers.	
MRI abdomen and pelvis without and with IV contrast (routine)	6		O
MR enteroclysis	6	This procedure requires specialized expertise that may not be available at all centers.	О
MRI abdomen and pelvis without IV contrast (routine)	5		0
CT abdomen and pelvis without IV contrast	4		
X-ray small-bowel follow-through	4		
US abdomen and pelvis	4		O
CT abdomen and pelvis without and with IV contrast	3		
X-ray contrast enema	3		
X-ray abdomen	3		
Tc-99m HMPAO leucoscintigraphy	3		
FDG-PET/CT abdomen and pelvis	3		
Rating Scale: 1,2,3 Usually not appropri	ate; 4,5,6 May be appropri	ate; 7,8,9 Usually appropriate	*Relative Radiation Level

Radiologic Procedure	Rating	Comments	RRL*

<u>Variant 7</u>: Child with known Crohn disease; stable, mild symptoms and/or surveillance.

Radiologic Procedure	Rating	Comments	RRL*
MR enterography	9	The procedures are equivalent alternatives, and only one should be performed.	О
CT enterography	7	The procedures are equivalent alternatives, and only one should be performed.	
MRI abdomen and pelvis without and with IV contrast (routine)	6		О
US abdomen and pelvis	6		О
CT abdomen and pelvis with IV contrast	5		
MR enteroclysis	5	This procedure may be appropriate, but there was disagreement among panel members on the appropriateness rating as defined by the panel's median rating. It requires specialized expertise that may not be available at all centers.	О
CT enteroclysis	4	This procedure requires specialized expertise that may not be available at all centers.	
MRI abdomen and pelvis without IV contrast (routine)	4		О
X-ray small-bowel follow-through	4		
CT abdomen and pelvis without IV contrast	3		
X-ray contrast enema	3		
X-ray abdomen	3		
Rating Scanler had pelvindy the tangen opri	ate; 24,5,6 May be appropria	tte; 7,8,9 Usually appropriate	*Relative Radiation

with TV contrast Radiologic Procedure	Rating	Comments	RRL*
Tc-99m HMPAO leucoscintigraphy	2		
EDC DET/CT 1 1 1 1	2		
FDG-PET/CT abdomen and pelvis	2		
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative
			Radiation
			Level

#### Summary of Literature Review

### Introduction/Background

Crohn disease (CD) is a chronic inflammatory disease involving the gastrointestinal tract, typically characterized by episodic flares and times of remission. Underlying structural damage progressively occurs over time with recurrent bouts of inflammation. Over the past several decades, there has been an increasing incidence of this disease. The specific etiology is unknown, but evidence suggests that an abnormal interaction between the gut and enteric microorganisms in a genetically predisposed individual may play a role in the pathogenesis. Patients usually present with either an abrupt or insidious onset of abdominal pain and diarrhea frequently accompanied by fever and weight loss. The small and large bowel are most commonly affected, but any portion of the bowel from the mouth to the anus may be involved. The small bowel is affected alone in about a third of patients, the colon alone in a somewhat higher percentage of patients, and combined involvement of the colon and the small bowel is seen in slightly fewer than a third of patients. Over time, there is a tendency for the disease extent to progress. A more severe disease course is seen with early age presentation (i.e., pediatric onset).

Clinical CD phenotypes have been described based on age of onset (pediatric, <17 years; adult, 17 to 40 years; older adult, >40 years), disease location (ileal, colonic, and ileocolonic), and disease behavior (stricturing versus penetrating versus inflammatory [nonstricturing, nonpenetrating]). Although disease behavior can change over time for a specific individual, clinical phenotypes provide important information to help determine clinical management.

Characteristic pathologic findings of CD in the gut include transmural granulomatous inflammation; deep ulcers that may progress to sinus tracts and fistulae; strictures that may lead to intestinal obstruction; and discontinuous involvement, with skip areas between diseased segments. Extraintestinal manifestations are common and include arthritis, cholelithiasis, ocular manifestations, dermatologic abnormalities, and, in children, growth retardation.

### Overview of Imaging Modalities

The diagnosis of CD is based on a combination of clinical, laboratory, endoscopic, histological, and imaging findings. No single diagnostic test allows unequivocal diagnosis. The imaging characteristics and distribution of disease provide supportive evidence for the diagnosis of CD. In addition, imaging is complementary to endoscopic techniques such as ileocolonoscopy, allowing diagnosis of disease when endoscopy is negative due to intramural disease without associated mucosal activity or due to lack of colonic and distal ileal involvement. Imaging is commonly called upon to distinguish CD from other conditions causing colitis. In particular, the presence of small-bowel involvement helps distinguish CD from ulcerative colitis.

In the last decade, many new therapeutic strategies have been developed to manage CD. The success of these treatments (which target specific phenotypes or subtypes of CD) depends on accurate diagnosis of the nature and extent of disease. Therefore, it is no longer sufficient for the radiologist to only detect the presence of CD; he or she must also accurately assess its subtype, location, and severity. This is particularly important in distinguishing segmental small-bowel narrowing due to active disease (which may be effectively treated with medical therapy) from fibrotic strictures (more amenable to stricturoplasty). Likewise, complex fistulas may be more effectively treated surgically, while simple fistulas usually respond to agents such as infliximab, which inhibit tumor necrosis factor (TNF). Therefore, accurate delineation of the frequently complex anatomy

of these lesions is essential.

Radiology has traditionally played a limited role in the long-term surveillance of patients with known CD because there is a poor correlation between clinical disease activity and the radiographic changes on fluoroscopic examinations. Newer imaging techniques, particularly CT enterography/enteroclysis and MR enterography, have been increasingly used for monitoring therapy due to their improved diagnostic capabilities over fluoroscopic examinations, especially in regards to assessing disease activity. Overall, it is well recognized that imaging is important in the evaluation of patients with complications of the disease, such as bowel obstruction, fistula formation, and abscess.

This narrative will discuss the role of various imaging modalities in the initial diagnosis of CD, during a suspected acute flare, and during a period of clinical remission/surveillance.

Initial Presentation, Suspicion of Crohn Disease; Overview of Variants 1–3

In this clinical scenario, CD is suspected as one of the diagnostic possibilities in a patient presenting for medical attention without a known diagnosis of CD. The purpose of imaging is to establish a CD diagnosis and exclude alternative diagnoses. Once CD is confirmed, the examination also serves to document the location, severity, and presence of complications at this initial presentation, which is helpful to establish the clinical phenotype. The acuity and severity at initial diagnosis may vary tremendously. Some patients may present acutely with severe illness mimicking acute appendicitis with fever, leukocytosis and/or signs/symptoms of an acute obstruction (Variant 1) whereas others may be relatively well with a history of indolent abdominal pain and diarrhea for an extended period of time (Variant 2). Patient presentation impacts the decision for the optimal imaging exam where patient tolerance for a given test and conspicuity of imaging findings is dependent on the acuity and severity of the clinical presentation.

Variant 1: Adult. Acute Initial Presentation. Fever, Severe Abdominal Pain, Vomiting, Leukocytosis. Suspected Crohn Disease

Variant 2: Adult. Nonacute or Indolent Initial Presentation. Mild to Moderate Abdominal Pain or Cramping. Suspected Crohn Disease

An initial clinical presentation as an adult (age 17–40) is common for CD with a peak age for occurrence at 20–30 years. When presenting as an adult, the site of disease tends to remain more stable over time as opposed to a pediatric presentation where the variation of location of involvement over time is much greater. Location is important, as ileal CD has been associated with future increased risk of stricturing and/or fistulizing complications and increased need for surgery. CD may also initially present in the older adult (age >40). Here, the colon is more typically involved with a more stable disease course and less debilitating disease. The available imaging options for evaluation for initial presentation are discussed.

### CT Enterography/Enteroclysis Versus Standard Abdomen/Pelvis CT

Computed tomography (CT) enterography/enteroclysis represents a CT examination with a specialized protocol in order to optimize the detection of more subtle pathology in the small bowel. Neutral contrast (by mouth for enterography and by nasoduodenal tube for enteroclysis) is given in large amounts to promote optimal distention of the small bowel. Combined with other modifications including thin collimation, multiplanar reconstruction, and intravenous (IV) contrast, this protocol maximizes technique to depict inflammatory changes in the small bowel related to CD. Most institutions and practices utilize CT enterography, whereas relatively few undertake CT enteroclysis due to the technical demands of the procedure related to placement of a nasoduodenal tube. Bowel distention of the jejunum is typically less at enterography than with enteroclysis but is considered acceptable with good technique.

It is difficult to precisely determine the test characteristics in CD exactly due to the lack of true reference standard as discussed in the previous section. However, the overall diagnostic performance for CT enterography/enteroclysis is excellent. When an endoscopic standard is utilized, sensitivity for CD ranges from 75% to 90%, with a specificity of >90%. Compared against other imaging modalities, CT enterography/enteroclysis represents an optimal option in most patients. The diagnosis of acute inflammation is made through visualization of thickened small bowel with mural stratification as well as extraenteric processes including engorged vasa recti/vascular, and surrounding inflammatory stranding. Because CT enterography/enteroclysis is a cross-sectional imaging modality, assessment for alternative diagnoses as well for the possible complications of CD including obstruction, abscess, and fistula can be made. With its intrinsic high spatial resolution and reproducible quality, state-of-the-art CT enterography represents one of the main imaging methods for initial diagnosis of small-bowel CD. CT enteroclysis is rarely used due to technical demands as previously stated. At many United States medical centers and practices, a combination of CT enterography and ileocolonoscopy has been advocated as the diagnostic algorithm of choice at initial presentation. Ileocolonoscopy can assess for colonic and distal ileal involvement and permits biopsies. The addition of CT enterography allows for assessment of the entire small bowel, including the distal ileum, and is helpful in establishing a CD diagnosis in cases where the terminal ileum and colon are not involved or when intramural disease is predominant, which can be unapparent at endoscopy.

On the other hand, standard abdomen/pelvis CT (without enterography or enteroclysis technique) may remain useful in the initial presentation of a

patient with CD, particularly in individuals with severe illness who may be unable to tolerate large amounts of oral contrast. Evidence of acute inflammation of an affected gastrointestinal segment can still be seen directly (i.e., bowel-wall thickening) despite the lack of optimized bowel distention or the use of positive contrast, which can potentially obscure the stratified mural enhancement. Besides assessing for inflammation, standard CT can also evaluate for CD complications including bowel obstruction, fistula formation, and abscess formation. Although positive contrast at standard CT may decrease evaluation for bowel inflammation, it is helpful for identification of fistulas and abscesses. Standard CT is also effective to assess for possible alternative diagnoses such as appendicitis.

Ultimately, the decision to use CT enterography, CT enteroclysis, or a standard abdomen/pelvis CT is dependent on the acuity and severity of presentation. In the acute presentation (Variant 1) where the patient is severely ill, a standard CT (without or with oral contrast) may be the preferred choice if the patient is unable to tolerate the large volume negative oral contrast requirement of CT enterography or CT enteroclysis. If the patient can tolerate the oral contrast in this acute setting, CT enterography is an excellent choice without substantially increasing the risk to the patient. However, in the acute presentation scenario (Variant 1), CT enteroclysis will have even more patient tolerance issues and has a higher risk profile (i.e., related to placement of a nasoduodenal tube and active instillation of contrast). In contrast, for patients presenting for evaluation of indolent abdominal pain and more chronic abdominal symptoms and with suspected CD (Variant 2), CT enterography or CT enteroclysis is preferable. CT enterography and CT enteroclysis each have shown increased sensitivity for subtle CD changes in comparison to standard CT. Both CT enterography and CT enteroclysis should be well tolerated in this patient group.

#### MR Enterography/Enteroclysis

Magnetic resonance (MR) enterography/enteroclysis combines contrast-enhanced MR imaging (MRI) scanning using fast imaging techniques with an enterography/enteroclysis protocol to optimize bowel distension. Additionally, the use of glucagon and/or prone imaging may help to decrease bowel peristalsis and thus artifact. As in the case of CT, enteroclysis technique at MR is much less frequently undertaken due to the technical demands of this examination.

MR enterography can accurately display bowel-wall changes in early CD. Characteristic bowel-wall changes suggesting active inflammation include bowel-wall thickening, high T2 mural signal, mural hyperenhancement with mural stratification, and hyperemic vasa recta. Besides inflammation, MR can detect complications for CD including obstruction, abscess, or fistula. MR may also depict alternative diagnoses such as appendicitis, although this may be more difficult than at CT. The lack of ionizing radiation at MR is a major advantage because of the likely need for multiple future examinations in patients diagnosed with CD.

Similar to CT enterography, the performance of MR enterography for CD is very good. Rates of sensitivity and specificity are 77% to 82% and 80% to 100%, respectively; test performance characteristics for active inflammation and complications are similar to CT enterography. However, the quality of MR examinations is much more variable, leading to increased interobserver variation as opposed to CT enterography. Overall, MR is more prone to respiratory and bowel-motion artifact, despite the use of glucagon (buscopan is unavailable in the United States), which may lead to suboptimal examinations and more difficult interpretations. Because of these limitations, unless the patient has had multiple, prior CT examinations for other reasons, it is best to start with a CT enterography as the initial evaluation in suspected CD.

The severity of patient clinical presentation should factor into the decision to perform MR. Severely ill patients are less likely to be able to hold still for the duration of MR examination, leading to increased artifact and poorer image quality. In these instances, other options may be preferable, particularly CT enterography or standard abdomen/pelvis CT (in those persons unable to drink large volumes of contrast). Thus, MR may be a less preferable choice in Variant 1 due to patient tolerance and quality issues in the severely ill patient and may be better tolerated in Variant 2 (indolent presentation). MR is good at depiction of exenteric complications such as fistula or abscesses, similar to CT. Due to the superior soft-tissue contrast, perianal disease including fistulation to the perineum is best evaluated at MR, using a small field-of-view, focused examination. However, it is often not possible to perform both MR enterography and a focused pelvic MR at the same scheduled time slot. First, after 70 to 80 minutes, the neutral contrast agent is often in the colon and can cause diarrhea. Second, many patients cannot tolerate a continuous, 45 to 50 minute MR examination.

#### <u>Ultrasound</u>

Transabdominal ultrasound (US) is a potential effective option in the initial diagnosis of CD. US can be accurate with appropriate expertise. The technique requires a systematic survey pattern of the entire bowel with graded compression (i.e., overlapping vertical sweeps with a high frequency 5–17 MHz linear transducer). Sensitivities for disease detection range from 75% to 94%, with specificities of 67% to 100% for CD with demonstration of wall thickening. The threshold for abnormal thickening is typically set at 4 mm. Besides wall thickening, findings include alteration of the US gut signature, presence of fat wrapping, and vascular changes. US contrast and Doppler techniques appear helpful in determining inflammation. Like MR, US holds advantages such as avoiding patient exposure to ionizing radiation related to evaluation. In addition, the real-time assessment of bowel pliability and peristalsis can be helpful in the diagnostic evaluation. With appropriate expertise, transperineal or endoanal US is also helpful at assessing perianal fistulous disease related to CD.

However, test characteristics decrease substantially with poor operator skill. In addition, patient factors such as guarding may not allow adequate compression with the US probe or large amounts of shadowing gas may obscure bowel, preventing an optimal examination. Location also affects diagnosis where higher sensitivities for terminal ileal involvement are seen compared to more proximal small bowel. False-positive diagnoses of abscesses are more likely at US. The determination for alternative etiologies may also be decreased.

#### Fluoroscopic Contrast Gastrointestinal Examinations

Historically, fluoroscopic contrast examinations of the gastrointestinal tract have been the primary imaging methods of choice in the diagnosis of CD. Small-bowel follow-through (SBFT) (with or without per oral pneumocolon) and enteroclysis can be used to evaluate the small bowel for evidence of thickening and active disease. In addition, internal fistulas can be detected, although other extramural complications such as abscess formation are only indirectly visualized which lead to decreased detection. It has become evident, however, with the emergence of specialized cross-sectional imaging modalities, that the performance of contrast fluoroscopy is not as accurate for active disease as compared to these other examinations. For small-bowel enteroclysis, training and experience with this technique is limited at most U.S. institutions and practices. Both SBFT and enteroclysis are hampered by their 2-demensional (2-D) perspective, whereby pathology can be obscured due to overlapping bowel loops. On the other hand, the real-time assessment for a fixed versus pliable nature of a segment of bowel can provide important ancillary information. Dependent on institutional and surgeon preference, there may be a role in delineating the preoperative anatomy for the surgeon, although there has been a marked decline in fluoroscopic use over recent years.

Likewise, a contrast enema can be used to evaluate the colon. However, endoscopy is the preferred initial examination of the colon in patients suspected of having inflammatory bowel disease. It is superior to the barium enema for the detection of early inflammatory changes and has largely replaced it as the initial diagnostic examination.

#### Abdominal Radiographs

Radiographs of the abdomen are limited in the initial diagnosis for CD. The ability to directly visualize bowel pathology is limited, and evidence for CD is instead inferred indirectly. There is little role if the patient is not acutely ill. Radiographs may be useful in severely ill presenting patients for assessment of complications related to CD, including evidence for free air in bowel perforation or evidence for obstruction.

#### Nuclear Medicine

Scintigraphic examinations include technetium hexamethyl propylene amine oxime-labeled white blood cell scan (Tc-99m HMPAO WBC) and fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET)/CT. In the majority of institutions, nuclear medicine currently plays little role in the initial evaluation/diagnosis of patients suspected of having CD. Examinations such as Tc-99m HMPAO WBC have demonstrated good sensitivities and specificities for intestinal inflammation, ranging in the mid 80% for both. However, the disadvantages of this examination, such as the decreased ability to depict and therefore detect alternative diagnoses and the complicated time-consuming technical aspects (i.e., labeling and handling of blood products) have limited its use in initial diagnosis. There may be a limited role for scintigraphy in disease surveillance after the diagnosis of CD has been established (see Variants 6 and 7).

#### Variant 3: Child. Initial Presentation. Suspected Crohn Disease

An initial clinical presentation as a child (age 16 or younger) occurs in up to 25% of CD patients. Disease involvement tends to be more extensive, often includes the upper gastrointestinal tract, and can change over time. As in younger aged adults, a main point of consideration when choosing an imaging modality for this age group is to minimize radiation exposure during evaluation. It is a major priority given the increased radiosensitivity of younger individuals as well as the likelihood of multiple necessary examinations over the course of a patient's lifetime. From this vantage point, MR enterography and US hold advantages over CT enterography/enteroclysis, standard CT, and fluoroscopic examinations. However, CT with low-dose technique may allow better quality examinations for initial diagnosis.

#### MR Enterography/Enteroclysis and Transabdominal Ultrasound

Both MR enterography/enteroclysis and US have shown excellent performance characteristics specifically in the pediatric population with respective sensitivities and specificities of 82% to 94% and 75% to 100% for MR and 74% to 93% and 78% to 93% for US. For US, the wall-thickness threshold varies from 1.5 to 3 mm as opposed to the 4-mm level in adults. The lack of exposure to ionizing radiation is a major advantage for these modalities. However, as in the case of adults, examination quality for both MR and US may decrease when the patient is acutely ill and unable to hold still. For US, operator skill is an additional factor to consider. For MR, examination quality may be more variable due to artifacts. In addition, MR enterography/enteroclysis is difficult to perform in young children (age <10) and may require sedation.

#### CT Enterography/Enteroclysis versus Standard CT

As with adults, CT enterography/enteroclysis has excellent performance characteristics. It has advantages of quick acquisition times, reproducible

examinations, and fewer examination quality issues than other modalities, particularly MR. These benefits are especially helpful in the pediatric population who may be less likely to cooperate with the examination. In severely ill children, diagnostic examinations can be obtained. Thus, CT is as a good first-line option in this situation. Radiation exposure is the main concern with dose estimates of 3.48 mSv in the pediatric population. Newer CT dose-reduction techniques, including iterative image reconstruction, hold promise in substantially decreasing radiation exposure. As discussed in the adult clinical variant section, standard CT without enterography technique remains a good option as it can depict CD (albeit with decreased sensitivity compared to CT enterography/enteroclysis) and allow assessment for alternative diagnoses.

### Fluoroscopic Contrast Examinations and Radiographs

As in the case of adults, fluoroscopic examinations have been the traditional imaging methods used to assess for CD. Similarly, the added diagnostic yield and ability of cross sectional imaging methods are leading to a gradual replacement of fluoroscopic contrast examinations. Although there is exposure to ionizing radiation with contrast studies, it is less than with CT on the order of 1.8 to 2.2 mSv. In pediatric presentation, upper gastrointestinal (GI) examinations may be useful to evaluate proximal GI involvement, which more commonly occurs in this age group. Abdominal radiographs are typically insensitive but may be helpful to identify obstruction or free air as in the adult.

#### Nuclear Medicine

As with adults, scintigraphy plays little role in the pediatric population in the initial diagnosis at most institutions. There may be a limited role in disease surveillance (see Variant 7).

Known Crohn Disease Presenting with Acute Exacerbation or Symptoms, or with Suspected Complications; Overview of Variants 4 and 5

In this clinical scenario, a patient with known existing CD presents with an acute episode (i.e., severe abdominal pain, vomiting, fever, and leukocytosis). The purpose of the evaluation is to assess for possible CD complications, including bowel obstruction, abscess, or fistula formation as well as to confirm the acute flare.

The specific comments made in Variants 1 and 2 for the various imaging modalities also apply in this clinical variant. Additional issues related to this clinical variant are presented below.

Variant 4: Adult with Known Crohn Disease; Acute Exacerbation Such as Fever or Increasing Abdominal Pain or Leukocytosis

CD is a chronic disease, with intermittent relapses. In the early years after diagnosis, inflammatory (nonstricturing/nonpenetrating) phenotypes predominate. Over time, however, anatomic damage results and a portion of CD patients migrate to a stricturing phenotype characterized by recurrent bowel obstructions, whereas another subset exhibits a penetrating phenotype with fistula and abscess formation.

#### CT Enterography/CT Enteroclysis versus Standard CT

Both CT enterography and standard CT are well suited for use in this acute clinical presentation. The CT nature of these examinations with high spatial resolution and fast acquisition of data allow for excellent detection of CD complications. CT enterography may not be feasible in severely ill patients or those with obstructive symptoms. Ultimately, patient tolerance for large volume neutral oral contrast administration factors in the decision between CT enterography and standard abdomen/pelvis CT (without or with administration of oral contrast). Fortunately, the bowel involvement in complicated CD is often not subtle in this clinical scenario and should be detected even without optimized technique. In addition, the intrinsic contrast of enteric fluid in fluid-filled, dilated bowel in this case may be helpful. CT enteroclysis is not indicated in this scenario as the potential harms are felt to outweigh the benefits in this acute setting.

Sensitivities for CT-based evaluation for stenosis/obstruction range from 85% to 94% with very high specificities. Sensitivities for abscesses are also very good, ranging from 86% to 100%. There is more variable performance for fistula detection with sensitivities ranging from 68% to 100%. One study showed a very low sensitivity of 20% for enteroenteric fistulas in their series. Particularly in the evaluation of a postoperative CD patient, it may be helpful to utilize a standard CT protocol and positive water-soluble contrast in order to assess for extraluminal contrast signifying a leak. Such cases may be difficult to diagnose with neutral contrast. A disadvantage of CT use in this scenario (Variant 4) is the exposure to ionizing radiation and the need for multiple examinations with recurrent flares. As dose reduction techniques advance, this may be less of a concern.

#### MR Enterography/Enteroclysis

The diagnostic ability of MR is similar to its CT counterpart with similar reported sensitivities/specificities for CD complications in various series. The sensitivity for stenosis/obstruction ranges from 87% to 92% with high specificities; detection performance remains high for abscesses (sensitivity 86%—100%). As with CT, the detection for fistulas is more variable, ranging from 40% to 100%. Although MR holds the advantage of avoiding ionizing radiation, evaluation of the acute abdomen may be better undertaken by CT in clinical practice. Acutely ill patients may not tolerate the longer acquisition times for MR and examination quality is more variable. In cases of bowel perforation, its ability to depict free

intraperitoneal air is decreased compared against CT. Peri-anal disease including fistulation to the perineum is best evaluated at MR. The superior soft-tissue contrast allows for accurate assessment of this region.

#### Transabdominal Ultrasound

With expert operator skill, US can detect CD complications in ranges similar to other cross-sectional imaging modalities. For example, in penetrating complications, sensitivities for fistulas have been reported at 71% to 82% with abscess detection at 80%. However, such performance falls rapidly with lesser degrees of operator skill. Detection of abscesses is likely decreased compared to CT where some anatomic areas are difficult to visualize related to the stomach or sigmoid/rectum. In addition, in situations of suspected bowel perforation, the detection of free intraperitoneal air is poor unless present in large amounts.

#### Fluoroscopic Contrast Examinations and Radiographs

Again, fluoroscopic contrast examinations and radiographs were traditionally used to evaluate complicating conditions of CD. However, as in the case of CD detection and activity assessment, cross-sectional imaging modalities have shown better sensitivity and specificity for extraenteric complications (i.e., fistulas, penetrating tracts, and abscesses).

#### Nuclear Medicine

Although some advocates of white blood cell scans have argued that this technique compares favorably with CT, MR, and US in diagnosing extraintestinal complications of CD, this view is not widely accepted. Nuclear medicine plays a subordinate role in patients with known CD who present with signs and symptoms of abscess, fistula formation, or bowel obstruction.

Variant 5: Child with Known Crohn Disease; Acute Exacerbation Such as Fever or Increasing Abdominal Pain or Leukocytosis

The specific comments in the adult Variant 4 apply here. Particularly for the pediatric population, limiting radiation exposure is a key consideration during examination choice.

Known Crohn Disease; Stable, Mild Symptoms, and/or Surveillance; Overview of Variants 6 and 7

In this clinical scenario, the purpose of the imaging evaluation is two-fold. One is to determine the presence or absence of disease activity in a relatively well CD patient. This is important because promoting situations of complete mucosal healing has been associated with sustained clinical remission, reduced hospitalization rates, and decreased need for surgery. Imaging may better direct treatment as it is known that symptomatology and other clinical parameters have shown poor correlation with disease activity. Secondly, when CD stenoses are detected, imaging can help determine whether the narrowing is predominantly due to active inflammation or due to fibrosis. This distinction is critical as the former responds to medical interventions, whereas the latter would be better treated surgically. Due to the cost and significant complications of agents such as infliximab, empiric treatment with these agents to make this distinction (i.e., does treatment improve the stenosis) is less attractive.

The specific comments made in first 2 clinical scenarios (i.e., initial presentation and acute exacerbation of known Crohn disease) for the various imaging modalities also apply in this clinical variant. Additional issues related to the clinical Variants 6 and 7 are presented below.

Variant 6: Adult with Known Crohn Disease; Stable, Mild Symptoms and/or Surveillance

### MR Enterography/Enteroclysis and Ultrasound

MR enterography/enteroclysis and US hold advantages over CT enterography/enteroclysis given the need for numerous examinations over many years over the course of the disease. As discussed in Variant 1, test performance is similar to CT enterography/enteroclysis. MR sensitivity and specificity for CD range from 77% to 82% and 80% to 100%, respectively. Because patients are not typically acutely ill, high examination quality can be more easily maintained in this scenario. In regards to active versus fibrotic strictures, at MR, findings of inflammation including mural enhancement, engorged vasa recti can suggest an active etiology. In addition, high T2 signal is very helpful. Conversely, the lack of these findings in a thickened segment may point to a more fibrotic cause. Very low T2 signal may also be helpful if present. The main discriminator between the 2 on imaging is the presence of proximal bowel dilation. Bowel distention proximal to the stricture has been seen to strongly correlate with the presence of fibrosis, whereas the absence of active inflammation involving the stricture does not necessarily confirm a fibrotic stricture. The distinction between an active versus fibrotic stricture can be difficult. Fibrotic strictures have been shown to enhance, presumably related to increased vascular permeability and increased blood flow rather than due to active inflammation, whereas active strictures can demonstrate mild proximal bowel dilation. To further confound this issue, active inflammation can coexist with fibrotic strictures.

US sensitivities for CD range from 75% to 94% with a specificity of 67% to 100%. US demonstrates strictures as fixed areas of luminal apposition with adjacent disorganized peristalsis. Increased flow suggests an inflammatory etiology, whereas lack of inflammatory findings and proximal bowel dilation may suggest a more fibrotic origin.

Pelvic MR may play a role in monitoring antitumor necrosis factor therapy, specifically in perianal disease.

### CT Enterography/Enteroclysis versus Standard CT

CT enterography/enteroclysis is also able to address the issues of this clinical scenario. The sensitivity for CD ranges from 75% to 90% with a specificity of <90% against an endoscopic standard. Similar to MR, the same morphologic parameters can be used at CT to distinguish between active or fibrotic strictures. The superior spatial resolution and fast scanning abilities lead to consistent high-quality examinations. However, the need for multiple studies over time for this clinical scenario would likely lead to prohibitive dose exposures. Dose-reduction techniques may help to minimize the disadvantage related to ionizing radiation in the future. The lack of bowel optimization for standard CT (with decreased sensitivities for mild disease) would argue against its use in this clinical variant.

#### Fluoroscopic Contrast Examinations and Radiographs

The performance of contrast fluoroscopy is not as accurate for active disease compared against cross-sectional imaging modalities. In this clinical application, both fluoroscopy and radiographs would be suboptimal.

#### Nuclear Medicine

Tc-99m HMPAO WBC has demonstrated good performance for the detection of disease activity, similar to other cross-sectional imaging modalities. Advocates propose that once the histological diagnosis of CD has been established, the disease activity can be reliably assessed by this technique. Its advantages include low radiation dose (approximately 3 mSv), lack of bowel preparation, ability to evaluate the small and large bowel simultaneously, and good patient acceptance. Disadvantages include the relatively high cost, the need to handle blood products, and the technical requirements related to in vitro labeling.

FDG tracer is taken up in areas of active inflammation and, when used with CT (PET/CT), allows improved localization. However, poor bowel distension can lead to false-positive examinations. More recently, PET/CT has been combined with CT enterography or enteroclysis techniques to further improve localization and reduce false-positives. Preliminary studies have shown that the correlation of FDG with CT enterography or enteroclysis may help with the differentiation of predominant active or fibrotic strictures and aid in developing management algorithms. Limitations include the radiation dose and the cost of the procedure. Further studies are needed to determine the role of this technique in CD before it can be more highly recommended.

Variant 7: Child with Known Crohn Disease; Stable, Mild Symptoms and/or Surveillance

The specific comments in the adult Variant 6 apply here. There may be additional issues related to the patient's ability to tolerate MR at a young age.

#### Summary of Recommendations

- Cross-sectional (CT and MR) enterography are the preferred imaging tests for the initial diagnosis, evaluation of acute flare, and surveillance
  of patients with suspected and known CD. For the initial examination in an adult patient with suspected CD, CT enterography is preferred
  as it is much less bowel and respiratory motion dependent. With a severely ill or young patient, the ability to perform any of these
  examinations may be impacted.
- High-quality MR enterography provides the opportunity to eliminate radiation exposure for children, young adults, and nonacutely ill adults
  while maintaining similar sensitivity to that of CT enterography. Institutional preference will be determined by availability, experience, and
  expertise.
- Fluoroscopic examinations (small-bowel series and barium enema) are used less frequently in the imaging of CD given the comparative advantages of cross-sectional imaging. However, they may still be helpful for some surgeons and their preoperative planning.
- Nuclear medicine examinations may be helpful in certain scenarios but are not widely used. Utilization will be determined by institutional preference.

#### Abbreviations

- CT, computed tomography
- FDG/PET, fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography
- IV, intravenous
- MR, magnetic resonance
- MRI, magnetic resonance imaging
- Tc-99m HMPAO, technetium-99m hexamethyl propylene amine oxime
- US, ultrasound

### Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
О	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv

<sup>\*</sup>RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

# Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

# Scope

# Disease/Condition(s)

Crohn disease (CD)

# Guideline Category

Diagnosis

Evaluation

# Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Nuclear Medicine

Pediatrics

Radiology

## **Intended Users**

Allied Health Personnel

Health Plans

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Utilization Management

## Guideline Objective(s)

To discuss the appropriateness of radiologic procedures in the diagnosis and evaluation of Crohn disease (CD)

## **Target Population**

Adult and pediatric patients with suspected or known Crohn disease (CD)

## **Interventions and Practices Considered**

- 1. X-ray
  - Small-bowel follow-through
  - Contrast enema
  - Abdomen
- 2. Computed tomography (CT)
  - Abdomen and pelvis, with intravenous (IV) contrast
  - Abdomen and pelvis, without IV contrast
  - Abdomen and pelvis, without and with IV contrast
  - CT enteroclysis
  - CT enterography
- 3. Ultrasound (US), abdomen and pelvis
- 4. Technetium-99m hexamethyl propylene amine oxime (Tc-99m HMPAO) leucoscintigraphy
- 5. Magnetic resonance imaging (MRI)
  - Abdomen and pelvis, without and with IV contrast (routine)
  - Abdomen and pelvis, without IV contrast (routine)
  - Magnetic resonance (MR) enterography
  - MR enteroclysis
- 6. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET)/CT, abdomen and pelvis

# Major Outcomes Considered

- Utility of radiologic examinations in differential diagnosis of Crohn disease (CD), diagnosis of CD complications, and in surveillance of CD
- Sensitivity and specificity of radiologic examinations

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

## Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

Of the 117 citations in the original bibliography, 71 were retained in the final document. Articles were removed from the original bibliography if they were more than 10 years old and did not contribute to the evidence or they were no longer cited in the revised narrative text.

A new literature search was conducted in August 2013 to identify additional evidence published since the *ACR Appropriateness Criteria*® *Crohn Disease* topic was finalized. Using the search strategy described in the literature search companion (see the "Availability of Companion Documents" field), 251 articles were found. Thirteen articles were added to the bibliography. Two hundred thirty-eight articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, the results were unclear, misinterpreted, or biased, or the articles were already cited in the original bibliography.

The author added 56 citations from bibliographies, Web sites, or books that were not found in the new literature search.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

## Number of Source Documents

Of the 117 citations in the original bibliography, 71 were retained in the final document. The new literature search conducted in August 2013 identified 13 articles that were added to the bibliography. The author added 56 citations from bibliographies, Web sites, or books that were not found in the new literature search.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

Study Quality Category Definitions

- Category 1 The study is well-designed and accounts for common biases.
- Category 2 The study is moderately well-designed and accounts for most common biases.
- Category 3 There are important study design limitations.

Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:

- a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description).
- b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence.
- c. The study is an expert opinion or consensus document.

# Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

### Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The American College of Radiology (ACR) Appropriateness Criteria (AC) methodology is based on the RAND Appropriateness Method. The appropriateness ratings for each of the procedures or treatments included in the AC topics are determined using a modified Delphi method. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. The expert panel members review the evidence presented and assess the risks or harms of doing the procedure balanced with the benefits of performing the procedure. The direct or indirect costs of a procedure are not considered as a risk or harm when determining appropriateness. When the evidence for a specific topic and variant is uncertain or incomplete, expert opinion may supplement the available evidence or may be the sole source for assessing the appropriateness.

The appropriateness is represented on an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate" where the harms of doing the procedure outweigh the benefits; and 7, 8, or 9 are in the category "usually appropriate" where the benefits of doing a procedure outweigh the harms or risks. The middle category, designated "may be appropriate", is represented by 4, 5, or 6 on the scale. The middle category is when the risks and benefits are equivocal or unclear, the dispersion of the individual ratings from the group median rating is too large (i.e., disagreement), the evidence is contradictory or unclear, or there are special circumstances or subpopulations which could influence the risks or benefits that are embedded in the variant.

The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating. To determine the panel's recommendation, the rating category that contains the median group rating without disagreement is selected. This may be determined after either the first or second rating round. If there is disagreement after the second rating round, the recommendation is "May be appropriate."

This modified Delphi method enables each panelist to an	ticulate his or her individual interpretations of the evidence or expert opinion without
excessive influence from fellow panelists in a simple, sta	ndardized and economical process. For additional information on the ratings process see
the Rating Round Information	document on the ACR Web site.
Additional methodology documents, including a more de	etailed explanation of the complete topic development process and all ACR AC topics car
he found on the ACR Web site	(see also the "Availability of Companion Documents" field)

## Rating Scheme for the Strength of the Recommendations

Not applicable

# Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

### Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Summary of Evidence

Of the 140 references cited in the *ACR Appropriateness Criteria*® *Crohn Disease* document, 1 is categorized as a good quality therapeutic study. Additionally, 139 references are categorized as diagnostic references including 15 well-designed studies, 42 good quality studies, and 28 quality studies that may have design limitations. There are 54 references that may not be useful as primary evidence.

While there are references that report on studies with design limitations, 58 well-designed or good quality studies provide good evidence.

# Benefits/Harms of Implementing the Guideline Recommendations

### **Potential Benefits**

Selection of appropriate radiologic imaging procedures for evaluation of patients with known or suspected Crohn disease (CD)

#### Potential Harms

- In the acute presentation scenario, computed tomography (CT) enteroclysis will have more patient tolerance issues and has a higher risk profile (i.e., related to placement of a nasoduodenal tube and active instillation of contrast) compared to standard CT.
- The quality of magnetic resonance (MR) examinations is much more variable, leading to increased interobserver variation as opposed to CT enterography. Overall, MR is more prone to respiratory and bowel-motion artifact, despite the use of glucagon, which may lead to suboptimal examinations and more difficult interpretations.
- Ultrasound (US) characteristics decrease substantially with poor operator skill. In addition, patient factors such as guarding may not allow
  adequate compression with the US probe or large amounts of shadowing gas may obscure bowel, preventing an optimal examination.
   Location also affects diagnosis where higher sensitivities for terminal ileal involvement are seen compared to more proximal small bowel.
   False-positive diagnoses of abscesses are more likely at US. The determination for alternative etiologies may also be decreased.
- Both small-bowel follow-through (SBFT) and enteroclysis are hampered by their 2-dimensional (2-D) perspective, whereby pathology can be obscured due to overlapping bowel loops.
- The disadvantages of nuclear medicine examination, such as the decreased ability to depict and therefore detect alternative diagnoses and the complicated time-consuming technical aspects (i.e., labeling and handling of blood products) have limited its use in initial diagnosis.
- Fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG) tracer is taken up in areas of active inflammation and, when used with CT (positron emission tomography [PET]/CT), allows improved localization. However, poor bowel distension can lead to false positive examinations.

### Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from

limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

#### Relative Radiation Level

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

# **Qualifying Statements**

## **Qualifying Statements**

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

# Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

### **IOM Domain**

Effectiveness

# Identifying Information and Availability

# Bibliographic Source(s)

Kim DH, Carucci LR, Baker ME, Cash BD, Dillman JR, Feig BW, Fowler KJ, Gage KL, Noto RB, Smith MP, Yaghmai V, Yee J, Lalani T, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® Crohn disease [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 22 p. [140 references]

# Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

1998 (revised 2014)

## Guideline Developer(s)

American College of Radiology - Medical Specialty Society

# Source(s) of Funding

American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

## Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Gastrointestinal Imaging

## Composition of Group That Authored the Guideline

Panel Members: David H. Kim, MD (*Principal Author*); Laura R. Carucci, MD (*Co-author and Panel Chair*); Mark E. Baker, MD; Brooks D. Cash, MD; Jonathan R. Dillman, MD; Barry W. Feig, MD; Kathryn J. Fowler, MD; Kenneth L. Gage, MD; Richard B. Noto, MD; Martin P. Smith, MD; Vahid Yaghmai, MD, MS; Judy Yee, MD; Tasneem Lalani, MD (*Specialty Chair*)

## Financial Disclosures/Conflicts of Interest

Not stated

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Fidler JL, Rosen MP, Blake MA, Baker ME, Cash BD, Charron M, Greene FL, Hindman NM, Jones

Appropriateness Criteria® Crohn disease. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 14 p. [117 references]
This guideline meets NGC's 2013 (revised) inclusion criteria.
Guideline Availability
Electronic copies: Available from the American College of Radiology (ACR) Web site
Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.
Availability of Companion Documents
The following are available:
<ul> <li>ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2015 Feb. 3 p. Electronic copies: Available from the American College of Radiology (ACR) Web site</li> <li>ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2015 Feb. 3 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2015 Feb; 2 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria® Manual on contrast media. Reston (VA): American College of Radiology; 2013. 128 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria® Crohn disease. Evidence table. Reston (VA): American College of Radiology; 2014. 61 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria® Crohn disease. Literature search. Reston (VA): American College of Radiology; 2014. 1 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria® Crohn disease. Literature search. Reston (VA): American College of Radiology; 2014. 1 p. Electronic copies: Available from the ACR Web site</li> </ul>
Patient Resources
None available
NGC Status
This summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This summary was updated by ECRI on July 31, 2002. The updated information was verified by the guideline developer on October 1, 2002. This summary was updated by ECRI on March 21, 2006. This summary was updated by ECRI Institute on June 2, 2010. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was updated by ECRI Institute on April 9, 2015.
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 $B, Katz\,DS,\,Lalani\,T,\,Miller\,FH,\,Small\,WC,\,Sudakoff\,GS,\,Tulchinsky\,M,\,Yaghmai\,V,\,Yee\,J,\,Expert\,Panel\,on\,Gastrointestinal\,Imaging.\,ACR$ 

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